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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,778	08/11/2000	Jay M. Short	DIVER1280-4	9253

7590 09/23/2003

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,778

Applicant(s)

Short et al.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,55,57-71 and 156 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,55,57-71 and 156 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 3/21/03 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Arguments Concerning Status of Claims 72-73

The applicant argues that claims 72 and 73 are not canceled or withdrawn from consideration. This argument is not persuasive because Paper No. 5, page 2, filed 10/10/01 clearly cancels these claims.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 3/21/03 have been accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-55, 57-71, and 156 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by the applicant's amendment to the claims filed 3/21/03.

In the amendment to the claims filed 3/21/03, "naturally-occurring" was added to the molecules recited in the claims as a limitation. This limitation to the molecules used in the methods were not present in the application or claims as filed. Nowhere in the application or claims as filed is there a description of using naturally-occurring molecules in the context of the claimed invention, as now instantly claimed. Therefore, because no actual support for the amendment was indicated by the applicant and no support could be found, the amendment adding this limitation to the claims constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-55, 57-71, and 156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. This is a new rejection necessitated by the applicant's amendment to the claims filed 3/21/03.

The use of "naturally-occurring" molecule in claim 54, etc renders the claims vague and indefinite because the metes and bounds of what constitutes "naturally-occurring molecule" in the context of the claims are unclear. Does this term encompass a molecule that is naturally present in cells, even the molecules in cells in which the cells were engineered to contain those molecules? If so, then the term encompasses molecules that naturally occur in combinatorial library cells because after replication of the cells, the molecules naturally occur there. Or, does the term only encompass molecules from cells that are completely natural, i.e., not touched by the hand of man? In which case essentially no molecules are encompassed because the molecules that are being referred to are usually genes and the genes derived from a gene expression library are not even close to natural because natural genes are present with other genes in large chromosomes which are essentially one molecule each. Gene expression libraries are artificial, consisting of only chromosomal fragments and thus do not contain "naturally-occurring" molecules. Accordingly, the first definition is the

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closest to being a usable definition and thus the claims were read on using that definition.

Claim Rejections - 35 USC § 102

Claims 54, 55, 58-63, and 67-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al (U.S. Patent No. 5,824,485). This rejection is maintained for reasons of record set forth in Paper No. 11, mailed 10/22/02. Applicant's arguments filed 3/21/03 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant argues that the Applicant's presently claimed invention is not drawn to the purposeful creation of novel activities by combinatorial techniques, but rather expression cloning of naturally-occurring molecules, such as DNA derived from a mixture of uncultivated organisms, and thus the claimed method recites screening environmental libraries containing sequences that are naturally occurring and which have not been rearranged or recombined in a laboratory setting. It is argued that the '485 patent describes combinatorial gene expression libraries and cloning genes, one of which is a known gene, from several different organisms into a single host cell.

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This argument is not persuasive for the following reasons. First, the claim limitations are now drawn to co-encapsulating a naturally-occurring molecule, followed by determining the ability of the molecule to modulate activity. As discussed above, the metes and bounds of what constitutes "naturally-occurring" in this context is unclear. The molecules from a combinatorial library can be considered to be naturally-occurring because they are naturally present in the cells of the combinatorial library. Thus, the claimed invention, as recited by the actual language of the claims, still reads on the teachings of Thompson et al. Additionally, because there is nothing in the claims that excludes cloning from known genes, the argument concerning this nonexistent limitation is not persuasive.

The applicants argue that they provide extrinsic evidence in support of the meaning of "combinatorial". This evidence is not persuasive because nothing in the claims as they currently exist excludes combinatorial libraries.

Therefore, in light of all available evidence including the rejection set forth in the previous Office Action and maintained above, the applicant's arguments and the arguments set forth above, the claimed invention is still anticipated by Thompson et al and the rejection under 102(e) is properly maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

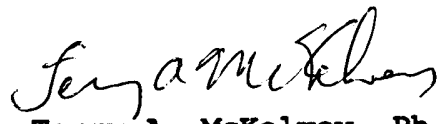
Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number

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is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Terry A. McKelvey, Ph.D.
Primary Examiner
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September 21, 2003